K001914

KURARAY CO., LTD.
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-6348-2603
Facsimile: +81-6-6348-2552

510(k) SUMMARY

1. Submitter

1) Name	KURARAY CO., LTD.
2) Address	1-12-39, Umeda, Kita-ku, Osaka 530-8611, Japan
3) Telephone	81(Japan)-6-6348-2603
4) Facsimile	81(Japan)-6-6348-2552
5) Contact person	Shinichi Sato Dental Material Department Medical Products Division
6) Date	June 18th, 2000

2. Representing (Subsidiary of KURARAY CO., LTD.)

1) Name	KURARAY AMERICA INC.
2) Address	200 Park Avenue, New York, NY 10166-3098
3) Telephone	(212)-986-2230
4) Facsimile	(212)-867-3543
5) Contact person	Koichi Kikuchi President

3. Name of Device

1) Proprietary Name	CLEARFIL REPAIR
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Resin-based dental adhesive system

4. Predicate devices:

1. CLEARFIL PORCELAIN REPAIR SYSTEM by KURARAY CO., LTD. (K873886)
2. CLEARFIL PORCELAIN BOND by KURARAY Co., LTD. (K871636)
3. CLEARFIL SE BOND by KURARAY CO., LTD. (K990040)
4. CLEARFIL PORCELAIN BOND ACTIVATOR by KURARAY CO., LTD. (K925404)
5. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)
6. PRIME & BOND 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR by DENTSPLY CO. (K962348)

5. Description for the premarket notification

CLEARFIL REPAIR is classified into the resin tooth bonding agent, CFR 21 Section 872.3200, because it is a device composed of materials such as dimethacrylate monomers intended to painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials.

This product is similar and substantially equivalent in design, composition and function to the similar products which are identified in the paragraph 4 of this summary; all of which are safe, effective and beneficial.

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6. Statement of the intended use

The intended purpose of this product is intraoral repair of fractured restoration made of porcelain, ceramics and composite resin such as crowns, inlays and onlays. This device is used for the following indications.

1. Intraoral repairs of fractured porcelain or composite facing crowns/bridges.
2. Intraoral repairs of fractured all ceramics restorations.
3. Intraoral repairs of fractured porcelain and composite inlays/onlays.

The above indications are similar and substantially equivalent to those of CLEARFIL PORCELAIN REPAIR SYSTEM and CLEARFIL SE BOND.

1. CLEARFIL PORCELAIN REPAIR SYSTEM by KURARAY CO., LTD. (K873886)
2. CLEARFIL PORCELAIN BOND by KURARAY Co., LTD. (K871636)
3. CLEARFIL SE BOND by KURARAY CO., LTD. (K990040)

7. Statement of the technological characteristics and safety

7-1 Components

CLEARFIL REPAIR is a resin-based dental adhesive system to be used for intraoral repair of porcelain or composite restoration, and consists of Etching agent, Primer, Bonding agent, Silan coupling agent, Masking composite and accessories. Etching agent, Primer and Bonding agent are components of CLEARFIL SE BOND; K-ETCHANT GEL, PRIMER and BOND. Silan coupling agent is the activator of CLEARFIL PORCELAIN BOND and CLEARFIL PORVELAIN BOND ACTIVATOR. Masking composite is a low viscosity opaque composite resin and substantially same to PHOTO CLEARFIL OPAQUER. Therefore the components are similar to those of the products in the paragraph 4 of this summary.

7-2 Performance

There is no ISO standard applicable to CLEARFIL REPAIR. The bond strengths to human enamel, human dentine, precious metal and porcelain are substantially equivalent to those of CLEARFIL SE BOND.

7-3 Chemical ingredients and safety

The chemical ingredients have been used in the following products allowed to be sold in U.S. market. The safety of this product is substantially equivalent to the predicated devices.

1. CLEARFIL SE BOND by KURARAY CO., LTD. (K990040)
2. CLEARFIL PORCELAIN BOND ACTIVATOR by KURARAY CO., LTD. (K925404)
3. PHOTO CLEARFIL OPAQUER by KURARAY CO., LTD. (K925383)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Koichi Kikuchi
President
Kuraray America, Incorporated
Subsidiary of Kuraray Company Limited OSAKA
200 Park Avenue
New York, New York 10166-3098

Re: K001914
Trade Name: Clearfil Repair
Regulatory Class: II
Product Code: KLE
Dated: June 21, 2000
Received: June 23, 2000

Dear Mr. Kikuchi:

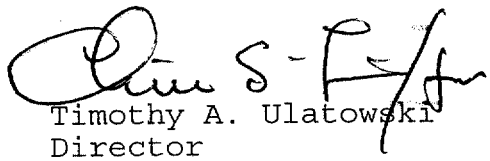
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001914

510(k) Number (if known): K001914

Device Name: CLEARFIL REPAIR

Indications for Use

CLEARFIL REPAIR is indicated for the following applications:
1. Intraoral repairs of fractured porcelain or composite facing crowns/bridges.
2. Intraoral repairs of fractured all ceramics restorations.
3. Intraoral repairs of fractured porcelain and composite inlays/onlays.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

for NSR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001914